

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 10/682,379 10/09/2003 Luis De Taboada ACULSR.005CP1 6100 20995 02/23/2006 **EXAMINER** 7590 KNOBBE MARTENS OLSON & BEAR LLP SHAY, DAVID M 2040 MAIN STREET ART UNIT PAPER NUMBER FOURTEENTH FLOOR IRVINE, CA 92614 3735

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

/	
v.	
\sim	

	Application No.	Applicant(s)			
	10/682,379	TABOADA ET AL.			
Office Action Summary	Examiner	Art Unit			
	david shay	3735			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
1) Responsive to communication(s) filed on Nove	mber 28. 2005.	·			
,	action is non-final.				
	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
. —	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.				
Disposition of Claims					
4) Claim(s) 1-21,23-26,28-30,37-41 and 44-66 is/are pending in the application.					
4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.					
6) Claim(s) <u>1-21,23-26,28-30,37-41 and 44-66</u> is/s	are rejected.				
7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/or	election requirement.				
Application Papers					
9)☐ The specification is objected to by the Examiner.					
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
, _					
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).					
a) ☐ All b) ☐ Some * c) ☐ None of:					
1. Certified copies of the priority documents have been received.					
2. Certified copies of the priority documents have been received in Application No					
3. Copies of the certified copies of the priority documents have been received in this National Stage					
application from the International Bureau (PCT Rule 17.2(a)).					
* See the attached detailed Office action for a list of the certified copies not received.					
Attachment(s)					
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date					
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5) Notice of Informal Patent Application (PTO-152) 6) Other:					
Paper No(s)/Mail Date 6) [Other:					

Applicant argues that the amendment filed December 11, 2003 was proper as it was within the time period set forth in 37 CFR 1.78 (a)(2)(ii). While this portion of the rule applies to claiming the benefit of the filing date of non-provisional applications (60/502,147 is a provisional application), 37 CFR 1.78(a)(5)(ii) does provide a similar time period for claiming the benefit of the filing date of non-provisional applications. Thus this objection has been withdrawn.

The rejection under 35 USC 101 has been maintained, as the recitation "an element interposed between the light source and the patient's scalp" positively recites the scalp.

With regard to the indefiniteness rejection, an electromagnetic field is a field generated by a moving electrical charge - see the attached definition of electromagnetic field from the Encyclopaedia Britannica - and thus cannot refer to a magnetic field alone. Thus the indefiniteness rejection has been maintained.

With regard to the apparatus claims, there is no structure in Tatebayashi et al, Chess, or Oron, that would prevent either from being used to blanch the scalp. The material of the applicator of Tatebayashi et al, Chess, or Oron are just as capable of being pressed on the scalp to blanch it as the material of applicant's device.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-21 and 23-25 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The positive recitation of "the scalp" is non-statutory.

Claims 47-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Page 3

In claims 47-49 exactly what is intended to be encompassed by the term "electromagnetic field" is unclear, as applicant seems to feel that this term encompasses magnetic energy alone.

These claims are too indefinite to apply art to.

Claims 1-6, 8-11, 14, 19, 24-26, and 28-30 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Tatebayashi et al.

There is nothing to prevent the apparatus of Tatebasyashi et al from being used on the head. The photons will scatter and after multiple scatterings, illuminate the entire brain. The inner cylinder is cross hatched as metal, and will therefore conduct heat from the sclap if brought into contact therewith.

Claims 1-10, 14-17, 19, 20, 24-26, and 28-30 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Chess.

Claims 1-6, 8-10, 14, 19, 23-26, and 28-30 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Oron.

Diode lasers inherently produce a small continuum of frequencies and thus produce plural wavelengths. Any slight delay in the actuation of the lasers will result in one wavelength being delivered subsequent the other

Claims 37, 38, 44-46, 51-54, and 57-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oron in combination with Streeter ('451). Oron teaches a device as set forth above. Streeter ('451) teaches the desirability of blanching the scalp before providing

phototherapy. It would have been obvious to the artisan or ordinary skill to transmit the light through blanched tissue in the method of Oron, since this allows more light to penetrate to the injury, as taught by Streeter ('451), thus producing a method such as claimed.

Claims 11-13 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chess in combination with Meserol and Kuesch et al. Chess teaches a device such as claimed except for the use of a glycerol. Meserol teach a device for applying light to the skin wherein the transmission of the light is enhanced by hydrating the skin. Kuesch et al teach producing skin hydration using glycol. It would have been obvious to the artisan or ordinary skill to employ glycol as taught by Kuesch et al in the method of Chess, since this increases the transmission of laser light through the skin surface, as taught by Meserol, thus producing a device and method such as claimed.

Claims 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chess. Chess teaches a method such as claimed except the use of air per se as the coolant. It would have been obvious to the artisan of ordinary skill to employ air as the coolant, since Chess teaches that any transparent gas can be used, and air is readily available and provides no unexpected result, thus producing a device such as claimed.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chess in combination with Eckhouse et al. The teachings of Chess are essentially those already set forth above. Eckhouse et al teach the use of a gel to cool the skin during light application. It would have been obvious to the artisan of ordinary skill to employ the gel of Eckhouse et al in the method of Chess, since this also provides cooling, and the particular form of the coolant of Chess can take many forms, thus producing a method such as claimed.

Claim 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oron in combination with Rosen et al and Meserol. Oron teaches a method as claimed except for the electroluminescent sheet. Rosen et al teach the use of a sheet of material including electroluminescent devices and teaches that optical fibers are also used in the prior art. Meserol teaches the use of a reflective coating to direct reflected light back to the skin. It would have been obvious to the artisan of ordinary skill to employ the electroluminescent sheet of Rosen et al in the method of Oron, since this also provides large area coverage, or to employ woven optical fibers, since these are known light emitting sheet material used for light application, and are not critical, and in either case to provide a reflective coating as taught by Meserol, since this will redirect reflected light back to the skin, as thus producing a method such as claimed.

Claim 55, 56, and 60-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oron in combination with Lo et al. Oron teaches a method as claimed except for the specific intensity, treatment interval, and treatment time. Lo et al teach that times several hours after the injury are among the ideal times to provide treatment. It would have been obvious to the artisan of ordinary skill to employ the claimed intensities, treatment intervals, and treatment times in the method of Oron, since these are known light intensities and treatment times for laser therapy, are not critical, and produce no unexpected result, and to estimate the time of the ischemic event, then begin delivering light to the stroke victim several hours after the ischemic event in the method of Oron, since this is a good time to begin treatment, as taught by Lo et al and since these times are not critial, thus producing a method such as claimed.

Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oron in combination with Streeter ('451) and Mueller et al. Oron teaches a method as claimed except for

the electroluminescent sheet. Streeter ('451) provides the teachings set forth above. Mueller et al teach the use of ultrasound in combination with laser light to encourage revascularization. It would have been obvious to the artisan of ordinary skill to employ the ultrasound and laser combination of Mueller et al in the method of Oron, since this enables revascularization, which would mitigate the effects of ischemia, since the new blood vessels would be able to deliver oxygen to the affected tissues, and in either case to transmit the light through blanched tissue, since this allows more light to penetrate to the injury, as taught by Streeter ('451), thus producing a method such as claimed.

Applicant's arguments filed November 28, 2005 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

Applicant's arguments with respect to claims 37-41, 44-46, and 50-66 have been considered but are most in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Application/Control Number: 10/682,379 Page 7

Art Unit: 3735

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco, can be reached on Monday through Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID M. SHAY PRIMARY EXAMINER GROUP 330